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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,070	10/15/2003	Henrik Hansen	10177-232	8917

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EXAMINER

PADGETT, MARIANNE L

ART UNIT PAPER NUMBER

1762

DATE MAILED: 12/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/687,070

Applicant(s)

HANSEN, HENRIK

Examiner

Marianne L. Padgett

Art Unit

1762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/21/2006 & 9/25/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17 and 20-37 is/are pending in the application.
- 4a) Of the above claim(s) 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-30, 32-35 & 36 is/are rejected.
- 7) ☒ Claim(s) 31, 35 and 37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1762

1. Applicants amendment have removed the 112 problems as noted in claim 30 on page 2 of the action mailed 12/21/2005, where his noted that the change to "comprising" language, instead of Markush terminology removes necessity for having mutually exclusive species & it is further noted that the disclosure on page 6 of the original specification while not using comprising language to describe the polymeric material, may be considered broad enough to do so as the "including" language used is also not exclusive.

Independent claims 20 & 34, have also been amended to narrow their scope such that it is an implantable medical device being treated, instead of any medical device, which may contact body tissue however previously rejected claim 36 was/is directed to a narrower species of implantable stance, so this issue has been covered previously an alternate scopes, and the rejected claims already reflect the issue of these changes.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 20-30, 34 & 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al (6,355,058 B1), in view of Escallon et al (4,749,125) as applied/discuss in sections 5 & 3 of the 5/6/04 & 3/29/05 actions, and further in view of Leidner et al. (6,056,993) or Shikani et al. (5695458), as applied in section 4 of the action mailed 12/21/2005.

As noted in the 3/29/05 action, Pacetti et al. in view Escallon et al. do not teach the use of the claims solvents, tetrahydrofuran or chloroform or toluene or acetone or isooctane or trichloroethane, in their electrostatically sprayed polymeric solutions, however on further review of the prior art it has been found that Leidner et al. teaches electrostatically spraying polymer solutions, where the polymers may be

Art Unit: 1762

silicone, high density polyethylene, polyurethane, polyester, polycarbonate,...or combinations thereof, with teachings on how to choose an organic solvent for a particular solution, wherefore the preferred silicone polymers, trichloroethane is the preferred solvent with halogenated alkanes generically taught as preferred, which is suggestive of chloroform, i.e. trichloromethane. Leidner et al. also optionally teach forming the composition such that it contains therapeutic ingredients, i.e. the equivalent of applicants' biologically active material. In Leidner et al., see the abstract; figure 1; col. 8, line 27-col. 9, line 56+; col. 10, lines 15-30 & 43-60, noting further only from her and polymer teachings including polyethylene glycol (PEG), poly (methylvinyl ether), polyacrylic acid, esters of poly (meth) acrylic acid, etc.; and col. 14, lines 42-67.

Leidner et al.'s technique is for actually making tubular prosthesis via deposition on mandrel, instead of merely coating them, however given that Pacetti et al. is coating stents, i.e. tubular prosthesis, via liquid electrostatic spraying that may include polymer binders of silicone or polycarbonate urethanes or polyethylene, etc., it would've been obvious for one of ordinary skill in the art to apply Leidner et al.'s teachings on solvents for electrospraying like materials for analogous purposes to the similar materials of Pacetti et al., particularly the use of halogenated alkanes, such as trichloroethane, when spraying silicones, to provide demonstrated effective solutions for the taught spraying technique, as taught in the combination of Pacetti and Escallon.

Alternately, Shikani et al. (458) teaches spraying polymer iodine coatings on medical products for disinfectant purposes, where successfully coated medical devices include catheters, tubes related to blood transfusions, needles and scalpel blades, all of which fit the criteria of being adapted for exposure to body tissue of the patient. Suggested polymers include polyethylene, silicone, polyvinyl chloride, polyethylene phthalate or polyesters, polypropylene, rubber, polyurethane, ethylene vinyl acetate, nylon, polycarbonate, cellulose esters, polystyrene, etc., where it is taught that polymers must be soluble in organic solvent solutions with useful organic solvents taught to include ethanol, aliphatic ketones (i.e.

Art Unit: 1762

dimethyl ketone), tetrahydrofuran (THF) and chlorinated hydrocarbons. A specific exemplary composition to be sprayed was polyurethane in THF with iodine. In Shikani et al. (458), see figures 1-2; col. 2, lines 1-14, including incorporation by reference of Domb et al. (5,344,411) & Shikani et al. (5,437,656) with further discussion of coating medical devices; col. 3, lines 33-44 & 63-col. 4, line 2; col. 6, line 45-col. 7 lines 10, 25-38 & 49-col. 8, line 2; and col. 9, line 33-40.

Given the teachings of Shikani et al. (458) on effective solutions for spraying biologically affecting polymer coatings using organic solvents, such as THF or chlorinated hydrocarbons, it would have been obvious to one of ordinary skill in the art to employ taught affective solvents for such polymer solutions for the analogous liquid polymer compositions for electrostatic spraying taught in Pacetti et al., who is silent on the topic of claimed solvents, because effectiveness for overlapping polymers, such as polyurethanes, is demonstrated for sufficiently analogous purposes thus providing an expectation of the effectiveness of these taught and claimed solvents in the electrostatic spraying process of the combination of Pacetti and Escallon.

4. Claims 20-30, 32-34 & 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bowlin et al. (2002/0081732 A1), noting that the filing date is October 18, 2001 with provisional applications 60/241,008 filed 10/18/2000 & 60/270,118 filed 2/22/2001, where (008) incorporates by reference SN 09/654,517 (abandoned, not IFW), SN 09/512,081(abandoned, not IFW) and 09/386273 (now PN 6,592,623), as applied in section 5 of the action mailed 12/21/2005.

Bowlin et al. (2002/0081732 A1) teach electrospraying or electrospinning, where the substrate or target, which is being deposited on may be grounded and charge supplied to the solution in its source chamber, where compositions are inclusive of claimed polymers such as polylactic acid (PLA) or poly (ethylene-co-vinyl acetate) used with chloroform, with teachings on importance of and effective choice of solvent (abstract; figures 1-2 & 8; [0067]; [0070- 75, especially 73]; [0082-92]; [0102- 0110, especially 102-103, 106-107 & 110]), however for this reference to be prior art the provisional documents must

Art Unit: 1762

supply appropriate support. In the (008) document, see figure 1; page 1-3; page 7 top; and claims 21-27, which supply the above relevant information, except for specific solvents, having only general teachings on the needs when selecting solvents. It is further noted that PN 6,592,623 incorporated by reference further illustrates relevant apparatus configurations in figures 2A, 2B & 7; col. 4-6 and in example 1 on col. 12-13 discusses the polymers PLA, polyglycolic acid (PGA) & copolymer of ethylene and vinyl acetate dissolves in solution with dichloromethane to be used for electrospinning. What information the two abandon applications supply, is not known at this time. Hence, while Bowlin et al. (732 A1) teach the claimed chloroform used in a claimed process, their support documents as available fall short of these, in that the chloroform is indicated to be used with the electrospinning, but no specific examples of solvent used with electrospinning is provided. However, it would've been obvious to one of ordinary skill in the art as the provisional (008) document teaches similar considerations in choice of solvent for both electrospinning and electrospinning, as well as teaching that electrospinning can be used in combination with electrospinning or by itself, to employ the taught polymer-chloroform compositions in the taught electrospinning as well as in the exemplified electrospinning, as the more general teachings suggest that such would have been applicable.

Specifically claimed parameters not set forth in the teachings of Bowlin et al. would have been expected to be determined by a routine experimentation, with variations expected due to particular choice of compositions including varying combinations of polymers, solvents and therapeutic agents, hence expected to be within or overlapping with claimed ranges.

5. Applicant's arguments filed 6/21/2006, and partially discussed above have been fully considered but they are not persuasive. Applicant's arguments appear to be based on their conception that all the references must apply their coatings to the same kind of devices, i.e. now all claims are requiring implantable medical devices to be the substrates, however this is not agreed with, since while end use while important to techniques chosen, is not the only factor which is important in choosing a deposition

Art Unit: 1762

technique, nor is it the only place that can provide teachings that are applicable to a deposition technique such as electrostatic spraying, where the matrix material being sprayed provides characteristic requirements for the technique employed, which would have been expected to be applicable across different end uses. In the patent Escallon et al. is teaching a generic electrostatic spray process which is generally useful for many applications & applicable to flowable materials, including biological compounds, polymeric compounds, etc., such that it's not mentioning a specific end use does not exclude it from the applicability to that end use, especially considering Pacetti et al. which is applicable to a specific end use, but is generally teaching the possibility of using various deposition (spray) techniques, inclusive of electrostatic spray, hence it would've been incumbent on one of ordinary skill in the art to review prior art electrostatic spray techniques, such as those of Escallon et al., with the intent to use them in the process of the primary reference, should they meet criteria commensurate with the process, which they have been shown to do. Choice of specific solution materials, would have been expected to be optimized for particular end use, and not provide patentable significance to the process per se unless they were not known to be used in such an electrostatic spray process &/or end use, or would have been expected to produce different results in the instant invention, i.e. provide unobvious results. Such has not been demonstrated for the rejected claims specific solvents with more generalized coating materials.

6. Claims 31, 35 & 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations (specific polymeric materials employed) of the base claim and any intervening claims.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing

Art Unit: 1762

date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

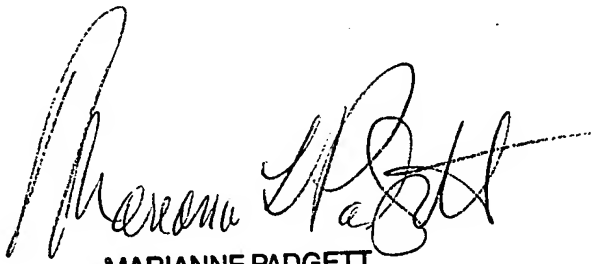
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne L. Padgett whose telephone number is (571) 272-1425. The examiner can normally be reached on M-F from about 8:30 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks, can be reached at (571) 272-1423. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MLP/dictation software

12/11/2006



MARIANNE PADGETT
PRIMARY EXAMINER